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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,090	05/30/2001	Katsuhiro Shinjo	PC9979ADAM	8350

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EXAMINER	
ULM, JOHN D	
ART UNIT	**PAPER NUMBER**
1646	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/870,090	Shinjo et al.
Examiner	**Art Unit**
John Ulm	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 5, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above, claim(s) *5-14 and 16-18* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-4 and 15* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *8, 10*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1) Claims 1 to 18 are pending in the instant application.

2) Claims 5 to 14 and 16 to 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 12, filed 05 May of 2003. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3) Claims 1 to 4 and 15, in so far as they relate to a polypeptide comprising SEQ ID NO:4, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12. The traversal is on the basis that SEQ ID NO:2 and SEQ ID NO:4 share a common technical feature because they contain an identical region. This is not found persuasive because they do not share a common utility which is based upon that common structural feature. The instant specification discloses that SEQ ID NO:2 and SEQ ID NO:4 correspond to the amino acid sequences of two human ion channels. One of ordinary skill would not reasonably believe that the region of these two amino acid sequences which is identical is sufficient to provide a functional ion channel protein. Because these are two different sequences a search for one of these two sequences would not be coextensive with a search for the other sequence in the absence of an admission by Applicant that

each is obvious in view of the other. Therefore, a search for both of these sequences in a single application would present an undue search burden.

The requirement is still deemed proper and is therefore made FINAL.

4) Applicant is reminded of the proper content of an abstract of the disclosure. A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or **speculative applications** of the invention and should not compare the invention with the prior art (M.P.E.P. 608.01(b)).

Where applicable, the abstract should include the following:

(1) if a machine or apparatus, its organization and operation;

(2) if an article, its method of making;

(3) if a chemical compound, its identity and use;

(4) if a mixture, its ingredients;

(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given. The abstract of the disclosure is objected to because it refers to clearly speculative applications of the claimed invention. There is absolutely no evidence of record which would support a conclusion that a protein or nucleic acid of the instant invention is in any way associated with any of the diseases or disorders listed in the abstract of the instant specification. A new abstract in compliance with M.P.E.P. 608.01(b) is required.

5) Claims 1 to 4 and 15 stand objected to as reciting an improper Markush Group for those reasons of record as applied to claims 1 to 11 and 13 to 17 in section 3 of Paper Number 9. M.P.E.P. 2173.05(h) states that "when the Markush group occurs in a claim reciting a process or a combination **(not a single compound)**, it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property". It further states that "[w]here a Markush expression is applied only to a portion of a chemical compound, **the propriety of the grouping is determined by a consideration of the compound as a whole**, and does not depend on there being a community of properties in the members of the Markush expression" (emphasis added). The instant claims recite an improper Markush group because they refer to two different individual compounds which do not reflect a single inventive concept. Correction is required.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6) Claims 1 to 4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims encompass a human protein as it occurs in nature.

7) Claims 1 to 4 and 15 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder of physiological process which one would wish to manipulate for a desired clinical effect.

It is clear from the instant specification that the receptor protein described therein as vanilloid receptor like (VRL)-2 is what is termed an "orphan receptor" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. Whereas one could readily employ a putative receptor protein of the instant invention in an assay to identify ligands thereto the information obtained thereby would be of little use until one discovers the identity of those physiological processes moderated by that putative receptor. Because the instant specification has

failed to credibly identify a specific physiological process which has been shown to be influenced by the activation or inhibition of a putative receptor protein of the instant invention an artisan would have no way of predicting what effects the administration of that ligand to an organism would have. If one can not predict the effects that the administration of a ligand of the putative receptor of the instant invention is going to have on an organism then it is unclear as to what practical benefit is derived by the public from the identification of that ligand.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", " [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting

license", " [i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a protein of as yet undetermined function or biological significance. There is absolutely no evidence of record or any line of reasoning that would support a conclusion the a protein of the instant invention is associated in any way with the plurality of disorders that are listed in lines 11 to 16 on page 3 of the instant specification. Until some actual and specific significance can be attributed to the protein identified in the specification as VRL-2, or the gene encoding it, the instant invention is incomplete.

The protein encoded by a DNA of the instant invention is a compound known to be structurally analogous to proteins which are known in the art as ion channels or ionotropic receptors. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which inhibit or induce its activity is clearly to use it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for VRL-2 then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

The disclosure in the instant specification that the VRL-2 protein described therein is structurally related to the capsaicin receptor VR-1 does not support a conclusion that VRL-2 will bind vanilloids and/or capsaicin. It is well known in the art that proteins belonging to the family

of ionotropic receptors can activated by a variety of compounds such as glutamate, glycine, acetylcholine and capsaicin, as well as other stimuli such as pH, voltage and ion differentials, heat and pressure. Because the differences between the amino acid sequence of the VRL-2 protein of the instant invention and that of hVR-1 are greater than the similarities, one would not conclude that these two proteins respond to the same spectrum of stimuli or modulate the same cellular processes. It was well known in the art prior to the making of the instant invention that receptor proteins belonging to the same structural family, such as the G protein-coupled adrenergic and dopamine receptors, could share substantial amino acid sequence similarity and still modulate completely different physiological processes in response to structurally related but different ligands. The administration of dopamine to an individual certainly has a profoundly different effect than the administration of adrenaline even though these two compounds are structurally related and the receptors for these two related compounds share substantial structural as well as amino acid sequence similarities. This position is further support by the text in lines 26 to 30 on page 6 of the instant specification, which shows that even within the family of VR-1 related proteins, the nature of the stimuli which activates these proteins can differ substantially from protein to protein. One would not reasonably conclude, based upon the limited amino acid sequence similarity between the VRL-2 protein of the instant invention and hVR-1 that the effects of clinical administration of an agonist to one of these receptors would be predictive of the clinical effects of administering an agonist to the other. Because one can not predict to which stimuli the instant receptor will respond by reviewing its amino acid sequence one can not conclude that

VRL-2 will have the same utility as VR-1 simply because these two proteins share a limited degree of amino acid sequence similarity.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8) Claims 1 to 4 and 15 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

9) Claims 1 to 4 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not provide the guidance needed to produce a "variant" polypeptide having anything less than the entire amino acid sequence presented in SEQ ID Nos: 2 or 4 of the instant application. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make the invention commensurate in scope with these claims.

The text in lines 9 to 12 on page 4 of the instant specification states that the term "variant", when applied to an amino acid sequence of the instant invention, includes "any substitution of, variation of, modification of, replacement of, deletion of or addition of one or more amino acids from or to the sequence providing the resultant polypeptide has VRL-2 activity". The current claim limitations are directly analogous to those of claim 7 of U.S. Patent Number 4,703,008 which were held to be invalid under 35 U.S.C. § 112, first paragraph, for want

of enablement in *Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd.*, 18 U.S.P.Q. 2d, 1016 (CAFC, 3/5/91, see page 1026, section D). In that instance, a claim to a nucleic acid encoding a polypeptide having an amino acid sequence sufficiently duplicative of the amino acid sequence of erythropoietin (EPO) so as to have a specified biological activity was held to be invalid under 35 U.S.C. § 112, first paragraph, for want of enablement. This limitation is directly analogous to the "variant" limitation of the instant claims. The disclosure upon which that claim was based described a recombinant DNA encoding EPO and a few analogs thereof. That disclosure differs from the instant specification because, whereas the instant specification describes two specific DNAs encoding a human VRL-2 protein, it does not describe even a single variant thereof. The court held that what is necessary to support claims of this breadth is a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims. For DNA sequences, that means disclosing how to make and use enough sequences to justify the grant of the claims sought. As indicated, the instant specification is even more limited than the '008 patent because it describes only two forms of a single protein and no variants thereof and, therefore, provides even less support than the '008 specification for claims of comparable scope and which were held to be invalid in that patent.

The instant specification discloses that a polypeptide having the amino acid sequence presented in SEQ ID NO:2 of the instant specification is a naturally occurring human ion channel protein which may or may not be involved with the transmission of sensations of pain. Because the instant specification does not identify those amino acid residues in the amino acid sequence of

SEQ ID NO:2 or 5 which are essential for biological activity and structural integrity of a VRL-2 protein and those residues which are either expendable or substitutable, a practitioner can not make and use a polypeptide lacking that entire sequence with any reasonable expectation that the altered protein would retain VRL-2 activity. In the absence of such structure-function information a practitioner would have to resort to a substantial amount of undue experimentation in the form of insertional, deletional and substitutional mutation analysis of over 800 amino acid residues before they could even begin to rationally design an VRl-2 variant polypeptide having other than a natural amino acid sequence and which retains VRL-2 activity. If fact, the instant specification does not provide a method through which an artisan can determine if a variant of the disclosed protein retains functionality because the instant specification discloses neither a demonstrated ligand for the instant receptor or the pathway through which it has been shown to signal. A receptor, by definition, must respond to a stimulus and transduce a signal. To determine if a derivative of a receptor has retained its function an artisan must be able to measure both of these activities. Since the instant specification does not identify a stimulus which has been demonstrated to activate or inhibit the disclosed protein, it is not possible to determine if responsiveness is retained in a variant of that protein.

Further, the instant application does not provide even a single example of a variant receptor protein other than the two naturally occurring receptor proteins that are disclosed in the instant application as SEQ ID NO:2, and SEQ ID NO:4. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that:

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

In the absence of both working examples of intentionally altered VRL-2 proteins and information on the ligand and signaling pathway of the disclosed protein an artisan could not alter a single amino acid residue in SEQ ID NO:2 with any confidence that the resulting protein will retain VRL-2 activity.

10) Claims 1 to 4 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is absolutely no written description in the instant specification of a variant of a protein comprising the amino acid sequence presented in

SEQ ID NO:2 or 4 of the instant application. In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Whereas the instant specification provides a detailed description of two isolated DNAs encoding two particular, naturally occurring, human proteins having very specific physical and structural properties, the instant specification does not provide a structural formula which is definitive of all, or even one "variant" of those two proteins as this term is defined in the instant specification. The

instant specification also fails to provide "a precise definition, such as by structure, formula, chemical name, or physical properties," of the genus of isolated VRL-2 polypeptides encompassed by these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11) Claims 1 to 4 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are vague and indefinite because the metes and bounds of the limitation "variants thereof" are undeterminable. As indicated above, the text in lines 9 to 12 on page 4 of the instant specification states that the term "variant", when applied to an amino acid sequence of the instant invention, includes "any substitution of, variation of, modification of, replacement of, deletion of or addition of one or more amino acids from or to the sequence providing the resultant polypeptide has VRL-2 activity". Because the specification does not identify a specific "VRL-2 activity" which is definitive of a "variant" then it is unclear as to what constitutes a "VRL-2 activity".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in-

> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

35 U.S.C. § 119(e)(1) states that:

> An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application. No application shall be entitled to the benefit of an earlier filed provisional application under this subsection unless an amendment containing the specific reference to the earlier filed provisional application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this subsection. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this subsection during the pendency of the application.

12) Claims 1 to 4 and 15 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by each of the Delany et al. patent publication (WO 00/32766, 08 Jun. 2000, cited by Applicant), the Masters et al. patent publication (WO 01/34805, 17 May 2001) and the Strotmann et al. publication (NATURE CELL BIOLOGY Vol. 2, pp. 695-702, Oct. 2000).

Delany et al. provided a written description of a protein identified therein as hVR3 and having an amino acid sequence (SEQ ID NO:5) which is 99.6% identical to SEQ ID NO:2 of the instant application. Claim 26 of that publication specifically anticipates claim 15 of the instant application.

Masters et al. provided a written description of a protein identified therein as hVR3 and having an amino acid sequence (SEQ ID NO:3) which is identical to SEQ ID NO:2 of the instant application. Example 11 of that publication specifically anticipates claim 15 of the instant application.

Strotmann et al. provided a written description of a protein identified therein as OTRPC4 and having an amino acid sequence which is 99.9% identical to SEQ ID NO:2 of the instant application. The experiment described in the fourth full paragraph on page 697 of that publication specifically anticipates claim 15 of the instant application.

Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 119(e) from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the now claimed invention. Because the instant application does not meet the requirements of 35 U.S.C. § 112, first paragraph, for those reasons given above and it is a divisional of application Serial Number 60/208,156, the prior application also does not meet those requirements and, therefore, is unavailable under 35 U.S.C. § 119(e).

13) Claims 1 to 4 and 15 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by the Dubin et al. patent (6,455,278 B1). provided a written description of a protein identified therein as hVR3 and having an amino acid sequence (SEQ ID NO:3) which is identical to SEQ ID NO:2 of the instant application. Example 11 of that publication specifically anticipates claim 15 of the instant application. Dubin et al. provided a written description of a protein identified therein as VR3 and having an amino acid sequence (SEQ ID NO:7) which is 99.9%

identical to SEQ ID NO:2 of the instant application. Example 5 of that patent specifically anticipates claim 15 of the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800